**Mental Health Drug Workgroup**
**4/29/05**
**2:00 – 4:00**
**Meeting Minutes**

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Meeting Started at 2:00

- To Do" and "Agreements" from 4/29/05 Meeting

  Agreements

  - The "evidence based minutes" reflect an adequate method of reporting out the workgroups review of the evidence in provider communications. The names will be removed for publication.

  To Do:

  - Take the weight-loss medication use (i.e. Topiramate) back to the AGs for a review. Dr. Martin will draft two "rare case" exceptions for Topiramate (i.e. related to the metabolic syndrome criteria and tried and failed taper of causative anti-psychotics).
  - Johnson & Johnson to report out on future Topiramate studies.
  - Dr. Bredin - Evidence-based gabapentin for restless leg syndrome review to be considered at next meeting
  - Ms. Blatt will provide the work group with the current status of the DOC mental health client transition for a June meeting to include the process flow and details.
  - Ms. Blatt will contact Mr. Adams and Mr. Lukivich to include them in all the preparation work done for the Mental Health client transition process.
  - Recommend labeling the pend letter - "Use of 2 or more 2nd Generation anti-depressants after 68 days.", plus other modifications to form.
  - Wait until after June before MAA implements the request letter (pend form) for use of 2nd antidepressants
  - What needs to be done before July 1 PDL implementation of 2nd Generation antidepressants to ensure that the efforts have been effective and there is criteria for NEW STARTS only. Put the discussion on an agenda item (like) tried and failed or is intolerant to a preferred agent.
  - Dr. Childs will modify the request letter (pend form) for the off-label use of anticonvulsants of gabapentin, levetiracetam, topiramate, and tiagabine as suggested by group.
  - HIPPA requirements for the forms - Mental Health Community - take to the AGs.

  **Agreements**

  - Dr. Ries' proposed the following - When there is adequate documentation for gabapentin in the primary disorder of anxiety with substance abuse/addition having tried and failed SSRI's and other lesser cost agents (e.g. carbamazepine, valproate) – MAA would approve this "off label" indication
  - Dr. Tomisser proposed the following - When there is adequate documentation for gabapentin for the prophylactic treatment of migraine headaches having tried and failed FDA labeled drugs and/or less costs alternatives (e.g. topiramate, propronolol or valproate)

**OLD BUSINESS**

- Minutes from previous meeting reviewed.
    - The minutes will be adjusted to show that "evidence based reviews" are paraphrased from the workgroup discussions. We agreed that the format is concise and can serve as a template for provider communications. For provider communications the author's names will be removed.
    - For the anti-epileptics the minutes will add to the ETOH and Substance abuse "valproate and carbamazepine have been found to be effective in good evidence based studies having A level."
- Reviewed the "agreement" list – No changes or comments.
    - Review the "to do" list – no changes noted.

**NEW BUSINESS**

- Draft Evidence-Based Reviews for consideration in communication to provider.

    - The workgroup discussed the indications of antiepileptic medications in ETOH and Substance Abuse and came to the following recommendations.
        - Overview: There is little evidence to support the initial use of second line anti-epileptics in ETOH/Substance abuse. The studies are largely case reports and non-controlled case series. Use of valproate and carbamazepine in ETOH and Substance withdrawal have been found to be effective with good evidence based studies having an "A" level of evidence. Use of gabapentin, topiramate, levetiracetam do not have good evidence based studies and generally have a "C" level of evidence with no head-to-head studies comparing standard therapies to these more expensive therapies. Most articles showed high %'s of side effects and intolerance with gabapentin.
            - "Off Label" use of Neurontin/gabapentin can be approved in acute ETOH/SA withdrawal with
                - Active pancreatitis or liver failure when indicated or
                - having tried and failed SSRI's and
                - lesser cost agents (e.g. carbamazepine, valproate) or
                - fear of needles to obtain blood levels for monitoring carbamazepine.
    - The workgroup discussed the indications of antiepileptic medications in anxiety.

        Overview - There is little evidence to support the initial use of second line anti-epileptics in anxiety. The evidence is generally "C" level with no head to head studies comparing standard therapies to the more expensive brand therapies. One meta-analysis, Pharmacological treatment of social anxiety disorder: a meta-analysis, Blanco C, Schneier FR, Depress Anxiety, 2003;18(1):29-40. Showed formal methods of interim monitoring adapted for meta-analyses suggested strongest evidence of efficacy for SSRIs. Gabapentin (effect size, 0.78; 95% CI, 0.29-1.27) was not statically significant. The stability of the SSRI effect size estimate in conjunction with other evidence for safety and tolerability and their ability to treat comorbid conditions supports the use of SSRIs as the first-line treatment. Direct comparisons of SSRIs vs. other promising medications deserve consideration.
        - "Off Label" use of Neurontin/gabapentin can be approved in the primary disorder of anxiety to:
            - concurrent substance abuse/addition – as first-time agent?
            - having tried and failed SSRI's and

- lesser cost agents (e.g. carbamazepine, valproate) or
- with other medically necessary reasons (e.g. fear of needles sticks necessary to monitor carbamazepine)

- The workgroup discussed the indications of antiepileptic medications in adjunctive therapy in mood stabilization.
  - Overview – There is little evidence to support the initial use of second line anti-epileptics in adjunctive mood stabilization. The evidence is generally "D" level with no head-to-head studies comparing standard therapies to the more expensive newer therapies. The group discussed the OSHU report that showed Gabapentin was no better than placebo in adjunctive therapy. The group agreed that second line antiepileptic medications are not effective. The group agreed that a taperering off period of 90 days would be appropriate in most cases. A provider could document a case to justify for more time in a taper.
    - "Off Label" use of Neurontin/gabapentin cannot be approved for adjunctive therapy in mood stabilization due to a lack of evidence

**Minutes and Para-phased Evidence Based Reviews from 4/29/05**

- Dr. Martin discussed the use of antiepileptic medications in treating the metabolic syndrome
  - Overview – A search of Pubmed back 10 years showed no literature to support the use of Topiramate in metabolic syndrome. There are case reports, 1-2 years in duration with up to 11 kgs. of weight loss. This weight loss can correct hyperglycemia in reported cases. Rainer School stated that they concentrate on calorie reductions over weight reduction drugs. The evidence is generally "D" level with no controlled studies or head-to-head studies comparing standard therapies to the more expensive therapies. The group discussed the literature of weight reduction and changes to metabolic parameters (i.e. in morbid obesity a 5% reduction can reduce hyperglycemia).
    - The group agreed that two "rare case" exceptions to "off label" use of Topiramate may be considered if 1) the client has metabolic syndrome and is unable to change from olanzapine or clozapine to diminish the metabolic side-effects (ziprasidone, aripiprazole, or possible risperidone are possibilities) or 2) they have a all 5 clinical indicators of metabolic syndrome. Dr. Martin will present these options to the group.
    - MAA will review the two "rare case" exceptions to "off label" use of Topiramate with legal counsel
    - The group discussed the high incidence of "metabolic syndrome" in the mentally ill population vs. the general population (75% vs 23%). The group asked whether the total cost of care or risk are taken into account in coverage decisions. MAA stated that after we get medical necessity the cost effectiveness is next
    - At this time MAA excludes weight loss drugs and this exclusion is in the state plan.
    - One member asked J&J whether there were on going studies related to Topiramate in weight loss and/or the metabolic syndrome. J&J will report back tot the committee.
- Dr. Tomisser discussed the use of Neurontin/gabapentin in headaches
    - Overview – A search of Pubmed showed only one study for Neurontin/gabapentin in chronic daily headaches. With migraine headaches there are two studies. She is trying to obtain the 2004 consensus guidelines from the American Academy of Neurology. There is "B and C' level evidence for prophylaxis of migraine with gabapentin and no comparisons with other

agents such as topiramate valproate and propranolol. There is some speculation that prophylaxis therapies are not economically sound unless the patient has a fair number of migraines.

- Dr. Bredin will discuss the use of antiepileptic medications in restless leg syndrome
- Mr. Lukavich sent the communication list to MAA. Ms. Blatt indicated that MAA and DOC are working on a process mapping of refills related to clients moving from DOC to MAA. Ms. Blatt indicated that many of the process are not electronic and the mapping will help to ensure "continuation of therapies". This mapping is in preparation of the DOC/MAA meeting June, 7th to discuss refill processes. Many members expressed interest in helping and the suggested that mapping should go beyond DOC/Jails. Ms Blatt will be contacting Dr. Farmer, Mr. Adams and Mr. Lukavish for their assistance.
- MAA announce that L&I will host a similar process of antiepileptic medications in neuropathic and non-neuropathic pain May 18th.
- The group discussed the second generation anti-depressant questionnaire findings (see handout). The group express concern but not surprise over questions 1/2 (unaware of duplication of rxs, 14% and 22% by another provider), 7 (use of algorithms in 29%), and 10 (willingness to discontinue any current care in 21-28%). One member stated that the question was not precise in use of algorithms. MAA stated the results were validated with face to face detailing. Direction of care is largely related to response and symptoms.
    - The group reviewed the provider communications for 2nd generation antidepressants and second line anti-epileptics. Title changes and clarifications of instructions were suggested. The forms will be adjusted and brought back to the group
    - Several members wondered if HIPPA allows the the sharing of mental health information to MAA who is not the payer of record for the mental health coverage only the payer of medications. The group suggested that HIPPA clarification be made on this issue.
    - The group reviewed the P&T PDL selections. Some members wanted to discuss the PA criteria for non-preferred drugs. Some members were concerned that the low endorsing status of psychiatry would present an administrative burden. MAA reminded the group that refill protections apply and that we are discussing only new starts. The PDL begins July 1, 2005 and that the group should discuss communication prior to that meeting. The group briefly discussed the PA criteria of tried and failed or intolerant to preferred drug (generic) or the other medically necessary rationale (i.e. side effects or drug/drug interactions). The group suggested more discussion on this topic.